REMARKS

By this paper, claims 39-44 have been added. Claims 14-44 are pending, of which claims 29-33 have been withdrawn.

In the outstanding Office Action dated January 26, 2005, claims 14-28 were rejected under 35 U.S.C. § 112, first paragraph. In so rejecting the claims, the Examiner stated that the specification "while being enabling for the use of certain inhibitors of TGFβ for the inhibition of cataract or after-cataract formation, does not reasonably provide enablement for the use of all inhibitors of TGFβ for the inhibition of such disorders."

As an initial matter, we note that in the Office Action of November 5, 2002, the Examiner indicated that claims 24-28 were allowable. We also note that the Examiner's comments in the Office Actions of November 5, 2002, August 6, 2003 and June 7, 2004 indicated that claims 14 -18 would be allowable if the word "preventing" was deleted from the claims. The word "preventing" has since been deleted from claims 14 and 24. We note that no reference to an enablement rejection was made in the Office Actions of November 5, 2002, August 6, 2003 and June 7, 2004.

We respectfully submit that the specification provides sufficient information to enable a person skilled in the art to carry out the invention defined by the claims. We additionally submit that a person skilled in the art could use the invention commiserate in scope with the claims without undue experimentation.

The claims of the present Application relate to the use of inhibitors of TGFβ to inhibit TGFβ-induced cataract or after-cataract formation in the eye of a mammalian subject. The claims also relate to ophthalmological formulations comprising an inhibitor of TGFβ.

As described in the specification, the inventors have found that TGFβ induces changes in the lens characteristic of certain forms of cataract and after-cataract, and have further found that

inhibitors of TGFβ inhibit these changes. As taught in the specification, any inhibitor of TGFβ may be used to inhibit these changes. The Examples set out in the specification demonstrate that inhibitors of TGFβ inhibit the changes in lens cells induced by TGFβ (See in particular Examples 2 and 4).

Any compound which inhibits TGFβ can be used in the method of the present invention. A range of different inhibitors of TGFβ are described in the specification. For example, page 2, lines 4-12, and page 4, lines 11-17.

Compounds with the property of inhibiting TGFβ are described in the prior art. In addition, we submit persons having the ordinary skill in the art would readily determine whether a particular compound is an inhibitor of TGFβ. Standard procedures for saying the biological activity of TGFβ (and therefore providing a ready means for determining whether a test substance is an inhibitor of TGFβ) were well known and in common use before the priority date of the claims of this Application. One common technique used before 1993, and used today, to assess TGFβ activity involves the use of mink lung epithelial cells. The mink lung epithelial cell line was established in 1964 and was, and is, readily available from the American Type Cultural Collection. This cell line is known as CCL-64 or Mv1Lu (NBL-7) cells. When TGFβ is added to mink lung cell cultures, the rate of cell proliferation is suppressed. To determine whether a test substance is an inhibitor of TGFβ activity, cells are cultured with TGFβ alone or with TGFβ plus the test substance. If the test substance reduces the suppressive effect of TGFβ on cell proliferation, it can be concluded that the test substance is an inhibitor of TGFβ.

The mink lung cell test is referred to in documents previously submitted to the Examiner, including Lucas et al., 1991 and Danielpour et al., 1989. A search of relevant scientific literature on the MEDLINE computer database reveals 99 articles published during the period of 1980 to

1993 in which the mink lung cell line was used in studies of TGFβ (a copy of the search strategy and search results is attached). The results of this search demonstrate that the mink lung cell test for determining TGFβ activity was well known in the art before 1993. For the Examiner's information, a copy of a selection of documents identified by the search published from 1990 to 1993 is enclosed with an Information Disclosure Statement (the documents included in the Information Disclosure Statement are the references 13, 17, 26, 39, 40, 43, 45, 49, 65, 67, 70, 72 and 80 in the results of the MEDLINE search). See in particular, Kelley et al., 1992 (document 26), Lucas et al., 1990 (document 72), Wolf et al., 1993 (document 13), Altman et al., 1990 (document 70) and Slager et al., 1993 (document 17). We also refer the Examiner to Yamaguchi et al., 1990 (reference 18 in the specification) and McCaffrey et al. 1992 (reference 19 in the specification), and copy of each of these documents is included in the Information Disclosure Statement filed with this response.

We, therefore, submit that using standard and routine techniques, a person of ordinary skill in the art could readily determine whether a particular compound is an inhibitor of TGFβ.

The Examiner has acknowledged that the specification is enabling for the use of certain inhibitors of TGFβ. We submit that in view of the teaching in the specification that all inhibitors of TGFβ are effective in inhibiting the formation of TGFβ-induced cataract and after-cataract in the eye, the specification must be enabling for the use of any compound which inhibits TGFβ.

At the top of page 3 of the Office Action, the Examiner has stated that it would require undue experimentation for a person skilled in the art to identify all TGFβ inhibitors that are capable of inhibiting cataract formation or after-cataract. We submit that all that is required is for a person skilled in the art to determine whether a particular substance is an inhibitor of TGFβ. Compounds with the property of inhibiting TGFβ are well known in the art. Further, a person

skilled in the art could determine by straightforward routine experimentation, for example, using the mink lung test referred to above, whether a particular compound is an inhibitor of TGFβ. As the Examiner has noted on page 3 of the Office Action, the level of skill of a person skilled in the relevant art is high.

We respectfully remind the Examiner that the case law clearly establishes that the fact some experimentation may be required does not mean that the claims are not enabled (see MPEP 2164.01).

At pages 3 and 4 of the Office Action, the Examiner has cited In re Dreshfield. We note that the holdings in In re Dreshfield were explained by the U.S. Patent and Trademark Office Board of Appeals and Interferences in Ex parte Reese (40 USPQ 2d 1221, a copy of which is attached). That decision made it clear that the section of In re Dreshfield quoted by the Examiner "bears little relation to the enablement provision." In that case, the U.S. Patent and Trademark Office Board of Appeals and Interferences found that the Examiner's reliance on In re Dreshfield to support an objection of lack of enablement was misplaced.

We submit that the Examiner's assertion that the claims are not enabled is not supported by relevant facts, it is mere opinion. We, therefore, respectfully submit that the Examiner has not established a *prima facie* case of lack of enablement. We further submit that it is within the skill of a person of ordinary skill in the art, based upon teachings of the specification, to carry out the invention as claimed in the present Application are the reasons referred to above.

We also respectfully submit that the specification provides a clear description of the use of inhibitors of TGFβ to inhibit TGFβ–induced cataract or after-cataract formation in the eye. The specification clearly describes how such compounds can be used to inhibit cataract or after-cataract formation, and clearly describes various classes of such compounds. We submit that any

experimentation that might be necessary for a person skilled in the art to determine whether a particular compound is an inhibitor of TGFβ is within the ordinary skill of those skilled in the art.

In the Examiner's comments, the Examiner has referred to the treatment of cataracts using surgery. We note that numerous patents have been granted for non-surgical methods of preventing or treating cataract. For example, we refer the Examiner to the following U.S. patents: 5,827,862, 5,665,770, 5,686,487, 5,589,464, 5,290,813, 5,519,054, 5,401,880, 5,399,573, 5,338,545, 5,284,874, 5,283,261, 5,279,836.

Each of these patents claims priority from an application filed before November 19, 1993 (the priority date of the claims of the present application). These patents demonstrate that methods of treating or preventing cataract other than by surgery are known in the art.

In the outstanding Office Action, claims 19-23 have been rejected under 35 U.S.C. § 102(b) as being anticipated by WO 92/17206. It is noted that WO 92/17206 is directed to the treatment of scarring and pharmaceutical compositions suitable for that use. On the other hand, claims 19-23 of the present application are directed to ophthalmological formulations comprising an inhibitor of TGFβ and an ophthalmologically acceptable carrier, but excluding conventional pharmaceutically acceptable carriers. Significantly, WO 92/17206 does not describe an ophthalmological formulation. Accordingly, we respectfully submit that claims 19-23 are novel over that document.

We respectfully submit that one cannot assume that a pharmaceutical formulation is equivalent to an ophthalmological formulation. As the skilled artisan would be well aware, the fluids that normally bathe the eye and lens have specific properties that should be mimicked in solutions that are applied to the eye. For example, the medium used as the vehicle for delivering

the active agent in eye drops to the surface of the eye should resemble the tear fluid that normally bathes that surface (see, for example, Bachman W G and Wilson G. *Invest Ophthalmal Vis Sci.* 1985; 26: 1484-1488; Gilbard P G, Rossi S R. and Gray Heyda K. *Am. J Ophthalmol.* 1989; 107: 348-355). Similarly, the vehicle used in the formulations intended for irrigation of the inside of the eye should resemble the aqueous humor that normally bathes the lens in the anterior chamber of the eye (Edelhauser et al., 1976). This study of the effects of various media on corneas from rabbits and human donors showed that media commonly used in pharmaceutical formulations, such as normal saline and Ringer's solution, caused considerable damage to the cornea, especially to the cells adjacent to the anterior chamber of the eye, and that this could be prevented by using media formulated to more closely resemble the aqueous humor. Accordingly, it is clear that ophthalmological formulations differ from the formulations described in WO 92/17206. Clearly, there is no reference in WO 92/17206 to an ophthalmological formulation comprising an inhibitor of TGFβ in an ophthalmologically acceptable carrier. Therefore, we respectfully submit that claims 19-23 are allowable.

New claims 39-44 are directed to ophthalmological formulations formulated for introduction into one or more chambers of the eye, the formulation comprising one or more inhibitors of TGFβ. WO 92/17206 does not anywhere mention formulations containing an inhibitor of TGFβ, wherein the formulation is formulated to be introduced into one or more chambers of the eye, let alone in an irrigation solution or viscoelastic solution suitable for ophthalmological use. Thus, we submit that new claims 39-44 are clearly novel over the cited art.

CONCLUSION

In view of the above remarks, Applicants respectfully request that the application be reconsidered, the claims allowed and the application passed to issue.

Respectfully submitted,

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1600] (Fed. Cir. 1988) (reversing award of attorney's fees against losing patentee where there was no evidence of "the type of conduct required for a finding of 'exceptional case'" and the patentee's case was "not totally without substance."). After consideration of all the circumstances, the conduct of the parties, and the evidence presented at trial, the court concludes that defendant's motion for attorney's fees should be denied.

IT IS THEREFORE ORDERED that defendant's motion for attorney's fees (Doc. #119) is denied.

U.S. Patent and Trademark Office
Board of Patent Appeals and Interferences

Ex parte Reese

No. 94-1477

Decided April 2, 1996
(Unpublished)

PATENTS

1. Patentability/Validity — Specification — Enablement (115.1105)

Patent examiner incorrectly rejected application claims for chemical compound under 35 USC 112 as based on non-enabling disclosure, since examiner apparently based rejection on subjective belief that claims are too broad and that specification requires more working examples, and did not adequately support this subjective belief with evidence or sound scientific reasoning, since examiner did not follow recent case law providing guidance on shifting burdens of persuasion in connection with enablement rejection, and since examiner's conclusion that specification does not contain sufficiently explicit disclosure to enable person having ordinary skill in art to practice claimed invention without exercise of undue experimentation is unsupported by facts.

Patent application of Colin B. Reese, serial no. 07/246,540, filed Sept. 14, 1988. From examiner's refusal to allow claims 18 and 24-33, applicant appeals. Reversed.

[Editor's note: The Board of Patent Appeals and Interferences has stated that this opinion was not written for publication, and that it is not binding precedent of the board.]

Jerry W. Berkstresser, of Shoemaker & Mattare, Arlington, Va., for appellant.

Before Winters, William F. Smith, and Metz, administrative patent judges.

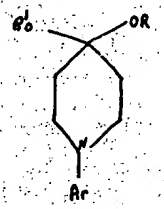
Winters, administrative patent judge.

This appeal was taken from the examiner's decision refusing to allow claims 18 and 24 through 33. Claims 20, 21 and 34, which are the only other claims remaining in the application, stand allowed. See the examiner's answer, page 1.

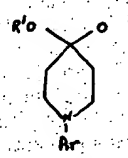
REPRESENTATIVE CLAIM

Claim 18, which is illustrative of the subject matter on appeal, reads as follows:

18. A protected compound of general formula:



wherein R [1] represents C_1 - C_4 alkyl, R is the deoxy residue of a protected carbohydrate compound, R being different from R', and Ar is a monocyclic aryl group having an electron-withdrawing substituent which renders the group acid-labile.



THE REFERENCES

In rejecting all of the appealed claims under 35 U.S.C. § 112, first paragraph, the examiner relies on the following references:

Penco et al. (Penco)	4,604,381	Aug. 5, 1986
Myers et al. (Myers)	4,912,094	Mar. 27, 1990
Stober et al. (Stober)	4,940,784	July 10, 1990
Furneaux et al. (Furneaux)	5,047,518	Sept. 10, 1991

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[1] Application for patent filed September 14, 1988.

THE ISSUE

The issue presented for review is whether the examiner correctly rejected claims 18 and 24 through 33 under 35 U.S.C. § 112, first paragraph, as based on a non-enabling disclosure.

DELIBERATIONS

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification and all of the claims on appeal; (2) appellant's main brief and reply brief before the board and "APPLICANT'S RESPONSE TO EXAMINER'S RESPONSE TO REPLY BRIEF"; (3) the examiner's answer and response to reply brief and "RESPONSE TO APPELLANT'S RESPONSE TO REPLY BRIEF"; (4) the prior art references cited and relied on by the examiner.

On consideration of the record, including the above-listed materials, we *reverse* the rejection of claims 18 and 24 through 33 under 35 U.S.C. § 112, first paragraph.

DISCUSSION

In rejecting all of the appealed claims under 35 U.S.C. § 112, first paragraph, as based on a non-enabling disclosure, the examiner focuses on these claim recitations: (1) R is the deoxy residue of a protected carbohydrate compound; (2) R is the 2' deoxy residue of a protected ribonucleoside; and (3) Ar is a monocyclic aryl group having an electron-withdrawing substituent which renders appellant's protecting group acid-labile. In view of those recitations, the examiner argues, the scope of enablement provided in appellant's specification is not commensurate with the scope of protection sought to be patented. We disagree.

[1] Apparently, this rejection stems from the examiner's subjective belief that appellant's claims are "too broad" and that the specification requires more working examples. That subjective belief, however, is not adequately supported by evidence or sound scientific reasoning.

As stated in *In re Armbruster*, 512 F.2d 676, 677-78, 185 USPQ 152, 153 (CCPA 1975), quoting from *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 369-70 (CCPA 1971):

> [I]t is incumbent upon the Patent Office, whenever a rejection on this basis [lack of enablement] is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

This the examiner has not done. In setting forth the statement of rejection in section (9) of the answer, the examiner (1) refers to the above-listed claim recitations; (2) argues that, in view of those recitations, the claims circumscribe a large area; (3) argues that more is required by way of working examples in the specification; and (4) argues that appellant does not provide "enumeration" of a sufficient number of compounds to support the relatively broad claims. That line of argument is long on opinion but short on evidence or sound scientific reasoning.

The examiner relies heavily on this passage from *In re Dreshfield*, 110 F.2d 235, 240, 45 USPQ 36, 41 (CCPA 1940):

> It is well settled that in cases involving chemicals and chemical compounds which differ radically in their properties it must appear in an applicant's specification "either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that 'the chemicals or chemical combinations' " included in the claims are capable of accomplishing the desired result. [citation omitted]

See the examiner's answer, section (9). We find it clear, however, that the examiner lifts that passage out of context from the pre-1952 *Dreshfield* opinion and attempts, improperly, to inject the same in a discussion centering on the enablement provision of 35 U.S.C. § 112, first paragraph. Careful review of the *Dreshfield* opinion reveals that the above-noted passage supports the court's holding that

> claims 15, 16, and 17 were properly rejected by the Primary Examiner on the ground that they are *broader than appellant's original disclosure* [emphasis added].

See *In re Dreshfield*, 110 F.2d at 240, 45 USPQ at 41. According to the court, those claims include compounds not disclosed in the specification as originally filed. Although 35 U.S.C. § 112, first paragraph, was enacted well after *Dreshfield* was decided, nonetheless, it appears that the above-noted passage from *Dreshfield* bears little relationship to the *enablement* provision of 35 U.S.C. § 112, first paragraph, but does bear relationship to the *description* provision of 35 U.S.C. § 112, first paragraph. For these reasons, the examiner's reliance on *Dreshfield* is misplaced. The examiner was remiss in not following more recent case law provid-

ing guidance on the shifting burdens of persuasion in connection with a rejection under the enablement provision of 35 U.S.C. § 112, first paragraph.

In section (10) of the answer, entitled "Response to Argument", the examiner belatedly discusses the factors listed in *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. & Int. 1986) pertaining to the issue of undue experimentation. According to the examiner, appellant's specification does not contain a sufficiently explicit disclosure which would enable a person having ordinary skill in the art to practice the claimed invention without the exercise of undue experimentation. As repeatedly pointed out by appellant in his reply brief, however, the examiner sets forth his conclusions and opinions unsupported by facts. Where, as here, the examiner's "Response to Argument" is not supported by evidence, facts, or sound scientific reasoning, we find that the examiner has not established a *prima facie* case of lack of enablement under 35 U.S.C. § 112, first paragraph.

The examiner's decision is *reversed*.

REVERSED.

U.S. District Court
Southern District of New York

Greenwich Film Productions S.A. v. DRG Records Inc.

No. 91 Civ. 0546 (JSM)

Decided September 5, 1996

REMEDIES

1. Monetary — Attorneys' fees; costs — Copyrights (§510.0909)

Prevailing copyright infringement plaintiff is entitled to recover only minimal attorneys' fees, since result achieved in case does not justify anything more than modest fee award, since defendant offered to settle case for $30,000 before action was filed, since it was unreasonable at that time for plaintiff to demand $1 million and refuse to lower that demand until eve of trial, and since plaintiff's unreasonable demand resulted in expensive litigation and it would be unfair to permit plaintiff to recover resulting costs.

JUDICIAL PRACTICE AND PROCEDURE

2. Procedure — Evidence — In general (§410.3701)

REMEDIES

Monetary — Attorneys' fees; costs — In general (§510.0901)

Evidence of settlement offer may be considered for purpose of determining reasonableness of claim for attorneys' fees in present copyright infringement action, since Fed.R.Ev. 408 permits admission of evidence of settlement negotiations when offered for purpose other than to prove liability, and since strong public policy considerations support admissibility of such evidence for purpose of determining reasonableness of claim for attorneys' fees, in that party to action in which attorneys' fees may be awarded should not be allowed to reject reasonable settlement offer and still recover full amount of attorneys' fees if it ultimately recovers little more than original offer.

Action by Greenwich Film Productions S.A. against DRG Records Inc. for copyright infringement. Following settlement, plaintiff seeks award of attorneys' fees. Plaintiff is awarded attorneys' fees in amount of $10,000.

Jeffrey Niederhoffer, of Orenstein & Orenstein, New York, N.Y., for plaintiff.

Michael Elkin, of Reid & Priest, New York, for defendants.

Martin, J.

Pursuant to 17 U.S.C. § 505, plaintiff, the prevailing party in a copyright infringement action, seeks attorney's fees and costs that are more than three times the amount of the damages plaintiff agreed to accept in full settlement of its liability claims. Plaintiff has agreed to settle its copyright claim for $50,149 and a related breach of contract claim for an additional $20,325.00. It seeks $259,188.25 in fees and expenses out of a total of $353,059.17 billed by plaintiff's counsel on this matter. Defendant for its part expended $117,591 in defense of this action.

This case presents an example of a problem that this Court has confronted in a number of cases in which the statute at issue provides for an award of attorney's fees to the prevailing party. The problem is that both sides lose sight of the fact that the amount of the attorney's fees should bear